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INAUGURAL PRIVATE & PUBLIC PARTNERSHIP WORKSHOP

WP4 LEADERSHIP

Module Leader: Jan Kremers
Module Facilitator / White Paper written by: Nikki L. Hafezi
University of Erlangen, Germany
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Schwabachanlage 6, 91054 Erlangen, Germany . telephone: +49 9131 85 34 595 . fax: +49 9131 85 344 15
nhafezi@europeanvisioninstitute.org . jan.kremers@uk-erlangen.de

Fostering Private & Public Partnerships

Organizational Overview / Purpose

European Vision Institute EEIG

EVI European Economic Interest Grouping (EEIG) has been formed in accordance with the Council Regulation (EEC) No 2137/85. The purpose of the grouping is to facilitate and/or develop activities representing its members by pooling resources, research interests and findings in order to reduce national fragmentation. The aim is to collectively produce quality results at a more efficient rate than those findings/results achieved by the members acting alone. The grouping is not intended to be a profit-making enterprise.

EuroVisionNet

One major project that the EVI developed and successfully received funding is the EuroVisionNet project (2008-2012). More information can be found on its website www.eurovisionnet.eu. EuroVisionNet comprises eight independent institutions/organizations representing six European countries. EuroVisionNet's primarily goals are to coordinate and consolidate vision research activities and policies in order to overcome national fragmentation and to avoid duplication of work. To achieves these goals, four objectives will be addressed during the life of the project (2008-2012): 1) scientific integration of European vision research 2) collaborating between public and private sector 3) establishing needs of vision community by means of policies and guidelines and 4) improving the communication between researchers, patients and general public. Nine work packages (WP) were designed to accomplish these four objectives.

WP4 - Fostering Private & Public Partnerships

Led by Prof. Jan Kremers, Department of Ophthalmology, University of Erlangen, Germany, this WP's goals are to convince and educate European public and industrial research institutions on the benefits of collaborating. In order to accomplish these goals, WP4 proposes to organize workshops with international vision research leaders, industry partners and other invested organizations/parties. The objective of these workshops would be to provide a platform for researchers and research-invested players to exchange research ideas and discuss ways for future collaborations.

Background

The basis of this WP is because there is an apparent lack of communication and motivation in the European vision research community that is needed to collaborate with industry and other potential funding and research partners. This lack is apparent when evaluating the funding portfolio/sources used to support basic and clinical research activities within European academic and medical institutions.

The motivation and need for diversifying the research-funding portfolio used to support all basic and clinical research at academic institutions simply do not exist in Europe. The reason is because most academic institutions mainly rely on federal funding. Hence, many European clinicians and researchers do not see the advantage of engaging with other possible funding or research collaborators besides their national or European governmental sources. Furthermore, many European researchers believe that receiving industrial funding is not desirable because the funding is not peer-reviewed. As exemplified in the United States,

collaboration with industry and other "outside" entities would substantially benefit European vision research by providing more opportunities. These benefits will be further identified and disseminated through the workshops that this WP facilitates.

In summary, European vision research institutions must be aware of the benefits of developing private and public partnerships. Some benefits include:

- Increased funding for and awareness of vision research
- Less dependency on single funding source (less risk)
- Technology transfer and commercialization activities
- Increased awareness of vision research developments, including knowledge transfer activities
- Maximizing the accessibility of multiple research disciplines within research institutions

Methods / Resources

Based on prior experience of attending lectures (>30 people) and workshops (<30 people), the WP4 leadership decided that to create an environment for discussion between the participants as well as the speakers, a workshop would be the ideal platform for this inaugural event. Additionally, to increase the likelihood of representation of multiple institutions using a limited budget, the leadership also decided to plan the workshop to coincide with a popular vision research congress (e.g. ARVO). Therefore, on Sunday, May 2, 2010, the private and public partnership (PPP) workshop was held in conjunction with the ARVO 2010 congress.

A total of 26 participants from the United States and European countries confirmed, and they represented six nations. To increase the possibilities of private and public partnership matches, the leadership tried to balance the audience with academic institutions, industry and other invested parties (e.g. governmental institutions, patient organizations, clinical research organizations, intellectual property and fundraising specialists, etc.) From these efforts, the participants represented the following: 13 academic institutions, 9 companies, 1 patient organization, and 1 governmental institution.

The biggest draw for the participants was the selection of the confirmed speakers. In developing the invited speaker list, the WP4 leadership agreed that it was imperative to have both European and American speakers. And, these speakers should represent a wide range of areas relating to establishing directed research projects with industrial partners and governmental funding sources. Therefore, several factors were considered in the final selection: 1) European academic researcher with knowledge and/or affiliation to EVI, 2) industrial representative with experience working with academia, 3) clinical research experience, especially relating to FDA and EMEA regulatory requirements , and 4) a funding source (e.g. private or public).

The confirmed speakers and their topics were (in order of the selection factors):

- Farhad Hafezi (University of Zurich): "Working with industry from a (European) academic perspective"
- David Luce (Reichert, Inc.): "Product Development Collaboration - When and Why?"
- Barbara Fant (Clinical Research Consultants, Inc.): "Global Clinical Trials: Challenges and Opportunities for Innovation"
- Paul Sieving (National Eye Institute): "National Institutes of Health - Public Private Partnerships (PPP)"

To acquaint all the participants, a biography booklet was created and electronically disseminated to all participants prior to the workshop. Each participant at the meeting was offered a printed copy. This booklet included a separate page for every participant (not just the speakers) with the following information: contact information, headshot, research interests, short biography, five key publications, h-index, number of times cited, total impact factor, and number of patents. For industrial representatives, the corporate overview including then number of employees, replaced the publication list, h-index, number of times cited and total impact factor. The concept behind this booklet was to allow the participants to prepare for discussions with potential collaborators at the workshop as well as provide an opportunity for later discussions.

Significance

Each of the presentations provided a platform for open discussions with the audience. Many of the participants provided their experiences regarding the presented topics, which aided greatly to the quality of the material presented. The following findings from each talk are as followed:

F. Hafezi: "Working with industry from a (European) academic perspective"

In summary, Prof. Hafezi presented many of the misnomers and common beliefs that Swiss academic researchers have about working with industrial partners. He believes that his Swiss impression also applies to many other European nations. Some beliefs that Prof. Hafezi addressed included (in no particular order):

- Industry having unrealistic timelines for results
- Researcher is "bought out" by industry and thus the researcher's data is biased
- Fearing that if funds are raised through industry, their governmental funds will be reduced

Prof. Hafezi believes that in Switzerland, academia in general does not provide the needed support to help a researcher through the translational research process. In other words, a researcher is forced to wear "too many hats" in the sense that a researcher must be a researcher, a lawyer and business person if he/she would like to commercialize his/her idea/research results.

As he has seen in the United States, many academic institutions have dedicated offices of technology and licensing (OTL) that assist researchers when they have results that can potentially commercialized and/or licensed. Furthermore, these OTLs assist with drafting, submitting and maintaining patents (and patent applications). Experienced individuals are hired specifically to garner the interest and support of industrial partners to help support research efforts. Much of this support is in the form of establishing direct research projects, licensing patents and creating spin-off companies. Currently in Switzerland, the interaction between the universities and the technology transfer offices is limited because the collaboration benefits are not fully understood. Prof. Hafezi posed this U.S. example as a best practice model that should be implemented in Swiss academic institutions if they plan to be competitive in future years.

Prof. Gregory Schultz, University of Florida, added that in order to convince the decision makers at the academic institutions that creating an environment for fostering translation research, there must be several points to consider:

- Everyone needs to be informed about the benefits of translational research / commercializing activities
- Patents should be considered as of the same importance as highly ranked published articles
- Recognition and rewards need to considered and provided for commercializing results, patents, spin-offs, etc.

Another finding in the United States that Prof. Hafezi addressed is that a substantial amount of funding is generated from the licensing and purchasing of patents that are generated from academic institutions. If the US model is adopted in Europe, then additional funding could be generated to foster future research efforts. Again, the interaction between Swiss/European universities and the technology transfer offices is limited because the collaboration benefits are not fully understood.

As a closing statement, Prof. Schultz added that from his institution alone, approximately $100 million USD/year is generated from the 120 licensing agreements. Two examples of highly grossing licensing agreements included the patents for Gatorade®, a non-carbonated sport's drink and Trusopt®, a sterile ophthalmic solution.

D. Luce: "Product Development Collaboration - When and Why?"

As both a scientists and an industrial representative Dr. Luce provided an overview of what he felt were issues and points for both academic researchers and other industrial partners to consider before engaging in research collaborations.

Some problems that Dr. Luce has experienced with working with past academic collaborators on research projects were: competing technology and/or products on the market, researcher's egos and venture capitalists' priorities. An enlightening comment included that in most small and medium-sized companies in the United States, investment firms (e.g. venture capitalists) heavily influence the research and development priorities. The priority for most venture capitalists is to receive quick return of investment. Therefore, researchers must understand the needs of the (real) funding source and be able to react when these questions arise.

Dr. Barbara Fant, Clinical Research Consultants, Inc., agreed that venture capital companies control the small-to-medium-sized companies. The bottom line for these companies is when do the investors receive their return of investment. Furthermore, another possible obstacle is the interaction between multi-disciplinary fields because the "culture and deemed respect" for the research are different. For example, engineers and surgeons may have different priorities when contributing to the development of a medical product. Both obstacles need to be considered throughout the duration of the research collaboration.

Prof. José Cunha-Vaz, AIBILI, feels that industry drives the market in terms of product development. And thus, he inquired about how can researchers identify what industries' priorities will be, or how can a researcher improve his/her chances of being identified for research collaborations with industry. Dr. Luce believes that from an industrial perspective, the best way for researchers to be identified for research projects are through speaking engagements and publications. Dr. Fant added that in her field of clinical trials, she is always looking for three types of collaborators: 1) highly acclaimed researchers, 2) political researchers to establish strategic alliances for future benefits, and 3) "work horses" - individuals who do a lot of work in a consistent manner.

Since the audience was representing both European nations and the United States, Dr. Luce also included, as a side note, the difficulty (and hesitancy) of working with certain countries because of their need to prove what was already proven by colleagues from a neighboring country. This need requires more time, money and effort than is typically necessary.

Furthermore, he also addressed what are some of the decision factors considered when deciding to collaborate: potential mutual benefits, indirect & direct costs, IP ownership & maintenance, timing, availability of resources (internally/externally), and publication rights. A misnomer for many researchers is that clinical utility is not necessarily a major cornerstone for choosing to collaborate. Some products in development may be applied to other needs/diseases/fields. In many cases, Reichert considers more global problems when choosing to invest funding, time and effort into direct research projects.

Dr. Luce addressed the three main types of collaborations for Reichert: 1) specific technical problems (product performance), 2) investigational (basic technical feasibility, new product concepts), and 3) clinical testing & evaluating of existing technology/ products. Regarding clinical testing collaborations, key components for success are to have regulatory affairs started early, fast response time and established communication between parties invested. A major bottleneck in the system is to overcome the IRB (Institutional Regulatory Board), and consideration for their requirements should always be of high importance.

Using one of their devices as an example, Dr. Luce provided a best practice where Reichert did not provide direct funding for any research projects/collaborations related to the ocular response analyzer (ORA). This practice was to reduce the false impression that any positive results were bought. Rather than funding, Reichert offered any research collaborator an open publication rights on any findings related to their device. The result was 125 peer-reviewed publications.

B. Fant: "Global Clinical Trials: Challenges and Opportunities for Innovation"

Dr. Barbara Fant provided a practical overview of her experience and best practices working with both academic institutions and industry in the area of ophthalmic-related regulatory affairs, clinical trials and product development. In her opinion, the benefits of research collaborations include: 1) pooling the expertise of other researchers, 2) access to new technology, 3) knowledge transfer possibilities and 4) improved clinical trial operations due to streamlined/centralized contracts.

When beginning discussions with potential partners, Dr. Fant recommends that for starters, researchers and industry should consider where they want to be at the end of their research collaboration. Although this consideration seems rather simple, the invested parties may have a different perspective of what they want from the collaboration. These perspectives should be considered, discussed and agreed upon before engaging any further. Collaborators engaged in private and public partnerships should also know that while the industrial partner provides the funding, the real client is the regulatory body (e.g. FDA). Therefore, the focus of the collaboration should always consider the requirements of the regulatory body.

The most common problem and biggest drawback that Dr. Fant faces when working with academic partners is the start-time needed to begin a clinical trial. Ways that she has managed to overcome this problem is to have a personal relationship with the academic institutions to clarify three matters regarding clinical trials: 1) confirm the number of patients (per trial), 2) precise start-up time (exact date) and 3) confirmed indirect costs. As a take-home message, Dr. Fant wants researchers to work as advocates at their universities to explain the need and benefits of translational research in order to establish a promising environment for collaborations with industry.

P. Sieving: "National Institutes of Health Public Private Partnerships (PPP)"

As the Director of the US National Eye Institute (NEI), Dr. Sieving provided both a scientific and governmental funding perspective as it relates to public and private partnerships. The NEI has an dedicated office of technology transfer (OTT) to help foster scientific partnerships to advance medical research related to eye health and eye disease treatments. More information can be found on their website: www.ott.nih.gov.

A best practice model that can simply be duplicated at any academic institution is NEI brochure of current technologies that are available for licensing and/or further developing (e.g. clinical trials). In the NEI Technology Transfer brochure, a summary is provided about the background, possible applications of the technology and development status. Therefore, a researcher/company can easily determine whether or not mutual interest is present.

However, in order for an academic institution to be able to maximize on the opportunities that this brochure may present, the institution must be administratively structured to handle requests and interests of industry and other academic institutions. As already mentioned by Prof. Hafezi, many European academic institutions are still at the stage of establishing working relationships internally (researchers and OTL), so once this step is established, the collection of current projects/technologies would come later. Also mentioned by Dr. Fant, the need to clarify three elements at any university (patients, start-up time and indirect

costs) would also need to be established prior to the dissemination of a brochure of this type. Therefore, if the two points that Prof. Hafezi and Dr. Fant are achieved, the likelihood of successful collaborations dramatically increases.

Expected Outcomes

During the planning stages of the inaugural PPP workshop, the EuroVisionNet event was a concern for the ARVO 2010 program committee. Since ARVO was also planning a similar topic for their advocacy luncheon, there was concern of overlapping interests and reduction of participation at either event. After lengthy discussions with the ARVO program committee, it was determined that there will be another PPP workshop in conjunction with ARVO next year (2011). To help with this collaboration, the WP4 leadership will include the ARVO program committee in the future planning stages of the the program and list of invited speakers in exchange for an official affiliation (e.g. SIG - Special Interest Group) with ARVO 2011. The expected outcome would be that more of the 2,400 ARVO members representing European institutions could benefit from this workshop through the official affiliation.

In respects to the workshops and the discussions among the participants, clinical research collaborations were of major interest. Based on follow-up discussions with some of the participants, two collaborations were identified:

- The University of Geneva's Chair of Ophthalmology will be retiring this calendar year (2010), and an industrial participant was concerned about the status of a clinical trial using their technology at this institution. Two of the participants of this company were present at the meeting. The facilitator of the meeting had worked with this company in the past, and she also knew the primary candidate for the University of Geneva's Chair of Ophthalmology, who was also present at the meeting. Putting both parties together, a future discussion will be scheduled to determine how to continue with the clinical trial efforts.

- The Jules Gonin Eye Hospital in Lausanne is highly interested in being more active with clinical research and industrial collaborations. Based on Dr. Fant's experience and best practice model about how to work with university administration to become more attractive for industrial collaborations and clinical trial research, the head of corneal and refractive unit will engage in future discussions with her.

Additionally, the input from the participants helped identify future speakers for next year's workshop and lecture. It is imperative to have individuals speak on their experience in order to exemplify the benefits of dedicating the time and effort to engaging in private and public partnerships to advance vision research.

Overview of WP4 Leadership

The Department of Ophthalmology at the University of Erlangen is chaired by Professor F. Kruse, Erlangen and is the home of one of the largest eye hospitals in Germany. Professor Jan Kremers joined the department in the beginning of 2006 and is responsible for the development of electrophysiological and psychophysical techniques in human subjects and in animals for retinal diseases.

This institution's research is focused on corneal transplantations and neuro-degeneration of the retina. The Erlangen-based collaborative research centre (Sonderforschungsbereich) is a nation-wide group of researchers that concentrates on ophthalmological problems like "Glaucoma including pseudoexfoliation syndrome (PEX)." The department is actively involved in six of the 12 center projects.

The main projects of Prof. Kremers that qualified him as the WP4 module leader, include the prioritization and coordination of research on age related retinal diseases and the FP5 Concerted Action "Photoreceptor Dynamics in Age Related Macular Degeneration (Photage)". Specifically, Prof. Kremers was the coordinator of "Photage," with over 20 years of experience in scientific research in ophthalmology. He was previously the laboratory director at the Department of Ophthalmology/Neuroscience at Novartis Institutes for Biomedical Research. And, in 2006 he co-founded a small private company ("Rhenovia") that is specialized in neurological and ophthalmological diseases.

To facilitate the deliverables of WP4, Mrs. Nikki L. Hafezi was selected as the most qualified individual because of her professional experience in the field of industrial relations in both the United States and Europe and her instrumental role in writing and submitting the EuroVisionNet proposal. Specifically, her professional background includes working with the US NSF (National Science Foundation) in the capacity of industrial relations for a biomimetic microelectronics systems engineering research center based in California.

Nikki L. Hafezi and Jan Kremers

The goal of her position was to create and manage directed research projects for academia and industry that would result in the generation and licensing of intellectual property (e.g patents) and translational research opportunities. After moving to Switzerland in 2006, Mrs. Hafezi now owns and manages a consulting firm in Zurich that provides fundraising, strategic planning, intellectual property management and business development services for academic and medical institutions to help foster research initiatives.

Closing

From the discussions and expected outcomes of the inaugural PPP workshop, the future goal is to conduct another workshop at ARVO 2011 in Fort Lauderdale. The difference is that the workshop will be accompanied by a special interest group (SIG) that will help educate scientists and clinicians interested in research about the best practice models regarding establishing and maintaining private and public partnerships.

As previously stated, it is imperative to still have a workshop in addition to the SIG because the registration for the workshop will help in obtaining biographies for the participants. This booklet is important to create and disseminate because it prepares the registered participants to meet with the other attendees to foster discussions during/after the workshop.

Specifically regarding the expected outcomes, Prof. Kremers and Mrs. Hafezi will follow-up with the participants to determine the status of their collaborations. These findings will also be presented at the next meeting at ARVO 2011.